

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 12 SEP 2005

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Applicant's or agent's file reference P36108WONCB		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/IB2004/003481		International filing date (day/month/year) 08.10.2004	Priority date (day/month/year) 09.10.2003	
International Patent Classification (IPC) or national classification and IPC A61K9/00, A61K9/10, A61K9/12, A61K31/165, A61K31/56				
Applicant JAGOTEC AG et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  11.04.2005		Date of completion of this report  12.09.2005		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Allnutt, S  Telephone No. +49 89 2399-		



**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/IB2004/003481

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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-17 as originally filed

**Claims, Numbers**

1-28 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-19,24,25,28
	No: Claims	20-23,26,27
Inventive step (IS)	Yes: Claims	
	No: Claims	1-28
Industrial applicability (IA)	Yes: Claims	1-28
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

The following documents are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

- D1: WO 03/074024 A1 (CHIESI FARMACEUTICI S.P.A; DAVIES, REBECCA, JAINE; GANDERTON, DAVID; L) 12 September 2003 (2003-09-12)
- D2: US 2002/018753 A1 (BLONDINO FRANK E ET AL) 14 February 2002 (2002-02-14)
- D3: US-A-6 054 488 (OLIVER ET AL) 25 April 2000 (2000-04-25)
- D4: WO 00/48587 A1 (NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H; CLARK) 24 August 2000 (2000-08-24)
- D5: US-B1-6 475 467 (KELLER MANFRED ET AL) 5 November 2002 (2002-11-05)

The documents considered in the present processing are consecutively numbered D1-D5; this numbering results from the citations D1-D5 found in the Search Report (SR) of the corresponding PCT application. It will be adhered to in the rest of the procedure. The cited passage(s) for each citation will be considered unless otherwise specified.

#### **Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

#### **Novelty**

1. The technical features of claims 20-23,26,27 are disclosed by documents D1 and D2 and therefore do not fulfill the requirements of Art 33 (2) PCT.
2. Regarding claim 26: A product is only defined by its components and not by its intended use. "Instructions" for using a product are merely a presentation of information which is not a technical feature defining the product.
3. The subject matter of claims 1-19,24,25 and 28 are not anticipated by prior art documents D1-D5 and therefore fulfill the requirements of Art 33(2) PCT.  
None of the prior art documents disclose a formoterol fumarate dihydrate (hereafter FFDH) having a water content of 4.8-4.28%wt.

**Inventive Step**

4. The prior art documents differ from the application only in that the formoterol fumarate dihydrate is not explicitly found to have a lower water content resulting from a drying step. The problem of stability regarding FFDH formulations is addressed in the prior art and is thought to be due to the presence of high concentrations of ethanol (cf. D3 and D4) and thus provides formulations with reduced levels of ethanol. D2 suggests the use of surfactants.

Thus the prior art provides several solutions to the problem.

The problem to be solved is seen as "how to provide an alternative stable aerosol formulations of formoterol fumarate"

The solution as provided by the applicant is the use of formoterol fumarate dihydrate having a water content of 4.8-4.28%wt.

D5 uses nedocromil salts to improve formoterol fumarate suspensions by reducing the moisture sensitivity of the active agent. However, it does not teach nor suggest reducing the water content of the active agent itself.

Therefore the application has provided an alternative way of stabilizing FFDH aerosol suspension.

**However**, the present application does not provide any evidence that the posed **problem has been solved** in the form of comparative stability data in order to show that this alternative provides a **special technical effect** over prior art. For instance D1 and D4 all provide formulations comprising the same components achieving the same effect, i.e. stability.

Therefore claims 1-19,24,25 and 28 in the absence of evidence that the problem has been solved, cannot be considered as involving an inventive step (Article 33(3) PCT).